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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,256	02/09/2004	Alfredo Berthel	PROCAPS 002C1	7158
7590	12/19/2007		EXAMINER	
Isaac A. Angres Suite 301 2001 Jefferson Davis Highway Arlington, VA 22202			SASAN, ARADHANA	
			ART UNIT	PAPER NUMBER
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			12/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/773,256	Applicant(s) BERTHEL ET AL.	
	Examiner Aradhana Sasan	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application***

1. The remarks and amendments filed on 09/04/2007 are acknowledged.
2. Claims 1-12 were cancelled.
3. Claim 13 was amended.
4. Claims 13-17 are included in the prosecution.

### ***Response to Arguments***

#### **Objection to the Specification**

5. Applicant's amendment of the abstract, filed 10/03/2007 is acknowledged.

#### **Rejection of claim 10 under 35 USC § 112**

6. The rejection under 35 USC § 112, second paragraph is rendered moot in light of applicant's cancellation of claim 10.

#### **Double patenting rejection of claims 1-12**

7. The double patenting rejection is rendered moot in light of applicant's cancellation of claims 1-12.

#### **Rejection of claims 1-13 under 35 USC § 103(a)**

8. Applicant's arguments, see Page 6, filed 09/04/2007, with respect to the rejection of claims 1-13 under 35 USC § 103(a) as being unpatentable over Chen et al. (US 6,383,471) have been fully considered but are not persuasive.

Applicant argues that the composition of claim 13 does not require ionizing agents and are distinguishable from Chen. Applicant argues that the invention of Chen requires the positive presence of a carrier comprising an ionizing agent, a surfactant

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having a specific HLB, and a triglyceride. Applicant argues that in the present invention, no surfactants or triglycerides are used in the solvent system and that the solvent system of the applicant's invention does not require the presence of the surfactants or triglycerides of Chen. Applicant states that none of the examples of Chen that contain glycofurol incorporate glycerin which is required in the solvent system of the applicant's invention.

However, the amendment of claim 13 is the replacement of the transitional phrase "comprising" with the transitional phrase "consisting essentially of". The transitional phrase "consisting essentially of" is construed as being equivalent to "comprising". According to MPEP 2111.03, "if an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention". Therefore, absent any evidence provided by the applicant regarding how the ionizing agent and surfactant found in the invention by Chen would materially change the characteristics of the applicant's formulation, the rejection of claim 13 will be maintained because of the open language "consisting essentially of" allows the inclusion of other components such as the ionizing agent and surfactant in the invention by Chen.

**Rejection of claims 14-17 under 35 USC § 103(a)**

9. Applicant's arguments, see Page 8, filed 09/04/2007, with respect to the rejection of claims 14-17 under 35 USC § 103(a) as being unpatentable over Chen et al. (US

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6,383,471) in view of Haskell (US 2002/0119200) have been fully considered but are not persuasive.

Applicant argues that there is no motivation in Chen in combination with Haskell to use the solvent system of the present invention which does not use ionizing agents . and that Chen in view of Haskell does not render obvious the invention as recited in the amended claims because Chen does not suggest the solvent system of the present invention.

However, since the independent claim 13 has the open language of "consisting essentially of" which allows the inclusion of other components such as the ionizing agent and surfactant in the invention by Chen. The motivation to combine the references is that COX-2 inhibitor (coxib) drugs are known NSAIDs. Haskell teaches the coxib drugs (Page 3, [0043]) and the inclusion of these drugs in the composition with NSAIDs as taught by Chen would have enhanced solubility and consequently enhanced drug bioavailability.

Therefore, the rejection of 5/2/07 is maintained.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 6,383,471).

The claimed invention is a pharmaceutical formulation for filling softgel capsules comprising: (a) a therapeutically effective amount of a non-steroidal anti-inflammatory drug (NSAID) selected from a group of propionic acid derivatives, acetic acid derivatives, fenamic acid derivatives, biphenylcarboxylic acid derivatives, and oxicams, and (b) a solvent system comprising a polyoxyethylene ether, glycerin and water and an alkaline hydroxide.

Chen teaches a pharmaceutical composition suitable for use in oral dosage forms which includes a therapeutic agent, a carrier that includes solubilizers, and a neutralizing agent (Abstract). The therapeutic agents include ibuprofen, naproxen, and celecoxib (Col. 6, lines 21, 35, and 40). These therapeutic agents are NSAIDs and celecoxib is a COX-2 inhibitor. Chen teaches that the carrier includes solubilizers such as ethers of polyethylene glycols such as tetrahydrofurfuryl alcohol PEG ether or glycofurol (Col. 31, lines 53-57). Soft gelatin capsules encapsulating the composition are the oral dosage forms (Col. 35, lines 3-5). Glycerin and water as optional components of a solvent system for a pharmaceutical agent are taught as a reference (Col. 2, line 7).

Chen does not expressly teach the percentages of the solvent components.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a pharmaceutical composition that includes encapsulated NSAIDs and a solvent system, as suggested by Chen, and modify the percentages of the solvent system components, and produce the instant invention.

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A person with ordinary skill in the art would have been motivated to do so because one would modify the percentages of the solvent system during the process of routine experimentation in order to achieve the desired dosage of the active and capsule size.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 13, the open language of "consisting essentially of" allows the inclusion of other components such as the ionizing agent and surfactant in the invention by Chen.

12. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 6,383,471), in view of Haskell (US 2002/0119200).

The teaching of Chen with respect to the encapsulated formulation of NSAIDs and a solvent system is stated above.

Chen does not expressly teach the rofecoxib, valdecoxib, or parecoxib.

Haskell teaches drugs of low water solubility and includes analgesics and anti-inflammatories such as parecoxib, rofecoxib, and valdecoxib (Page 2, [0042], and Page 3, [0043]).

Instant claims 14 (with the limitation of rofecoxib), 15 (with the limitation of valdecoxib), 16 (with the limitation of celecoxib), and 17 (with the limitation of

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parecoxib), would have been obvious to one with ordinary skill in the art over the teaching of NSAIDs and celecoxib by Chen, in view of the teaching of the specific COX-2 inhibitors by Haskell.

One of ordinary skill in the art would have been motivated to do this because the COX-2 inhibitor (coxib) drugs are known NSAIDs and their inclusion in the composition as taught by Chen in view of Haskell would enhance the solubility and consequently the bioavailability of the drug.

### ***Conclusion***

13. No claims are allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-




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9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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